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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,156	05/30/2000	Lawrence B. Sandberg	97-489-US-P	1346

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EXAMINER
BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/580,156	Applicant(s) Sandberg et al.
	Examiner Michael Borin	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 17, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above, claim(s) *15-18* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-14, 19, and 20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: Sequence Listing

DETAILED ACTION

Status of claims

1. Claims 1-20 are pending.

Applicant's election, with traverse, of Group I, claims 1-11, 13,19,20, is acknowledged. The traversal of the restriction requirement is on the grounds that there is no burden of search. Examiner agrees that Group VII, claims 12,14 should be rejoined with Group I. In regard to other product groups, applicants have not provided any reasons why they consider not burdensome additional search of differently classified products. Further, in regard to methods of use, a reference teaching composition comprising the elected peptide would not necessarily teach or suggest its use in a particular method, such as method of enhancing tissue elasticity. Accordingly, the search of Groups drawn to methods of use would require additional literature data bases search. The restriction requirement is deemed to be proper and is therefore made FINAL. Claims 15-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 15-18 and amendment of claims 1-14,19,20 to read on elected invention are requested.

With respect to the election of species requirement, applicants elected peptide SEQ ID No. 48. Insofar as the elected compound has been found to be neither anticipated nor rendered obvious by the prior art, the Examiner has extended his

search to peptides SEQ ID No. 15, which is another species of the genus of claim 12. In addition, a rejection made in the parent case, 09/039308 which addresses peptide SEQ ID No. 11, is also applied. Claims reading on the elected species are claims 1-14,19,20.

Sequence Listing

2. The computer-readable sequence listing filed 10/3/00 is not proper. See Raw Sequence Listing Error Report attached. Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing.

Claim Rejections - 35 U.S.C. § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States...

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1,3,4,6-10 are rejected under 35 U.S.C. 102(b) as anticipated by Yamauchi et al (JP 08225594).

The instant claims are drawn to pharmaceutical compositions comprising elastin fragment Phe-Gly-Pro-Gly (SEQ ID 11).

Yamauchi teaches peptide Phe-Gly-Pro-Gly (i.e., the peptide of SEQ ID 11 of the instant invention) and compositions comprising said peptide. See abstract. Aqueous solutions of Phe-Gly-Pro-Gly demonstrated mitogenic effect in mouse spleen cells and *in vivo*. See abstract and Tables #1, 5 (show *in vitro* effect), #3 (shows *in vivo* effect). The reference uses the peptide in concentration sufficient to achieve therapeutical effect (see col. 12, table #1).

In regard to type of pharmaceutical carrier limitations in claims 3,4,9,10 the instantly claimed peptide is in an aqueous solution (see col. 11 and Table #3), i.e., in a carrier appropriate for pharmaceutical delivery, topical or subcutaneous delivery in particular.

In regard to suggested use limitation in claims 3,6-8, suggested use limitations do not impart patentability to composition claims where the composition is otherwise anticipated by the prior art. Intended use of the composition are of little relevance in determining the patentability of the composition.

4. Claims 5,11 are rejected under 35 U.S.C. 103(a) as obvious over Yamauchi et al (JP 08225594) in view of Scaffidi (US 5,079,003). This embodiment of the instant invention is drawn to particular carriers for topical applications of the claimed compositions. The peptide Phe-Gly-Pro-Gly is a fragment of elastin and it is taught in Yamauchi. The reference teaches aqueous compositions of the peptide but does not other types of pharmaceutically acceptable carriers. Scaffidi teaches that compositions comprising soluble elastin hydrolyzates are used as cosmetic preparations in such forms as lotions or creams. See '003, abstract and claim 1. It would be obvious to use the elastin fragment Phe-Gly-Pro-Gly in a carrier other than aqueous solution taught in Yamauchi, which would be appropriate for topical delivery, such as a lotion or a cream, because Scaffidi teaches that elastin hydrolyzates are

useful in cosmetic preparations and because selection of a particular carrier is within the skill of the ordinary worker as a part of the process of normal optimization.

5. Claims 1,12,13 are rejected under 35 U.S.C. 103(a) as obvious over Nakamura et al (US 5,449,661).

Instant claims are drawn to pharmaceutical composition comprising peptide VVPG (Seq. ID No. 15).

The reference teaches angiotensin converting enzyme inhibitors and methods of their pharmaceutical use. In particular, the reference teaches peptide VVPP (col. 8, Table 2, and claim 2). The referenced and claimed peptides differs their C-terminal residue (proline and glycine, respectively).

It is well known that several amino acids are considered to conservative substitutions of proline. These amino acids include alanine and glycine. See Atlas of Protein sequence and structure, p. 96. Therefore, in view of the equivalence of Pro and Gly, the use of Gly in place of Pro in the peptide of primary reference would have been obvious to one of ordinary skill in the art at the time the invention was made. In addition, as follows from the Table 2 in US 5,449,661, Pro is not a critical residue and can be conservatively substitutes (compare lines 3,5,6 of the Table).

6. Claims 2,4,5,9-11 are rejected under 35 U.S.C. 103(a) as obvious over Nakamura et al or Yamauchi et al. The references are applied as discussed above.

The references do not expressly or suggest the claimed concentration range or ways of formulating composition. Absent some teaching to the contrary however, the determination of particular ranges employed is within the skill of the ordinary worker as a part of the process of normal optimization. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components and adequate ways of formulating compositions because these are art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature.

Conclusion.

7. No claims are allowed

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

April 5, 2002

mlb